

## REMARKS

### **I. INTRODUCTION**

Claims 18-23 and 29-34 are pending in this application. The applicant thanks the Examiner for his allowance of claims 20, 21 and 29-34. In view of the following remarks, it is respectfully submitted that all of the presently pending claims are allowable. It is respectfully submitted that no new matter has been introduced.

### **II. THE 35 U.S.C. §103 REJECTIONS SHOULD BE WITHDRAWN**

Claim 18 stands rejected under 35 U.S.C. 103(a) as unpatentable over U.S. Patent No. 6,500,158 to Ikeguchi (hereinafter "Ikeguchi"). Claim 19 stands also rejected under 35 U.S.C. 103(a) as unpatentable over Ikeguchi as applied to claim 18, and in further view of U.S. Patent No. 5,411,495 to Willingham (hereinafter "Willingham"). Furthermore, claim 23 stands rejected under 35 U.S.C. 103(a) as unpatentable over Ikeguchi as applied to claim 18, and in further view of U.S. Patent No. 5,289,831 to Bosley (hereinafter "Bosley").

The Examiner stated, in support of the rejection, that Ikeguchi shows the invention as claimed except for the second catheter, but that it would have been obvious to one of ordinary skill in the art to modify the system of Ikeguchi to include two catheters in order to provide for patients who need simultaneous treatment of both ureters. (*Id.*, p.3). The applicant respectfully disagrees with the Examiner argument.

Claim 18 recites an apparatus for isolating urine from a urinary bladder, the apparatus comprising:

a first catheter positionable in the patient's first ureter, the first catheter including a proximal end and a distal end, the proximal end of the first catheter including a ureter to catheter seal, the distal end of the first catheter being capable of passing through

the patient urinary sphincter; and

a second catheter positionable in the patient's second ureter, the second catheter including a proximal end and a distal end, the proximal end of the second catheter including a ureter to catheter seal, the distal end of the second catheter being capable of passing through the patient urinary sphincter and the distal ends of the first and second catheters being capable of connection to an external urine collection container.

(*Emphasis added.*)

In contrast, Ikeguchi purports to describe a method and apparatus for treating a kidney by reducing pressure within the Bowman's capsule. The apparatus includes a catheter which is inserted into the ureter. A balloon coupled to the catheter is inflated to occlude the ureter and a proximal end of the catheter is attached to a vacuum source and a collection system to lower the pressure in the Bowman's capsule to adjust the pressure gradient in the glomerulus and increase the glomerular filtration rate. (Ikeguchi, col. 5, lines 16-34 and 56-63). As indicated by the Examiner, Ikeguchi includes no showing or suggestion of the use of such a method or apparatus on more than one kidney and Ikeguchi provides no motivation for such a modification.

"To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *MPEP 143.03*; see also *In re Royka*, 490 F.2d 981, (CCPA 1974). Claim 18 recites a first catheter positionable in a patient first ureter and a second catheter positionable in the patient second ureter. As indicated by the Examiner, Ikeguchi does not disclose or suggest a second catheter. The single catheter of Ikeguchi simply delivers a negative pressure to the kidney to reduce pressure in the Bowman capsule. No suggestion is made that the addition of a second catheter in the second ureter would be more effective than serial application of single catheters to the ureters - or that this simultaneous application of vacuum pressure to the Bowman's capsules of both kidneys would not be harmful - in any case where a patient required treatment of both kidneys.

It is respectfully submitted that, for a rejection under § 103, the Examiner has the initial burden of establishing a *prima facie* case of obviousness. *See MPEP 142*. Contrary to the requirements for *prima facie* obviousness, the Examiner has neglected to demonstrate that the proposed solutions to the deficiencies of Ikeguchi were taught or suggested therein or by any other prior art. Thus, the Examiner has not met his initial burden and it is respectfully submitted that this rejection under § 103 is improper and should be withdrawn.

It is respectfully submitted that, in addition to the failure of the cited prior art to show or suggest each and every element of claim 18, the prior art must also supply the motivation for the proposed modification or combination (i.e., adding a second catheter in the second ureter). Ikeguchi purports to describe a device for the treatment of an individual kidney and is in no way directed to preventing contact between urine and the bladder. No mention is made of a need to treat both kidneys and there is clearly no showing or suggestion that such treatment should be done simultaneously. Thus, Ikeguchi neither shows nor suggests any second catheter located in a second ureter. Furthermore, a statement that the proposed modifications of the prior art would have been within the ordinary skill of the art at the time the claimed invention was made is not sufficient to establish a *prima facie* case of obviousness without some objective reason to combine or modify the teaching of the references. *MPEP 2143.01*; *see also In re Kotzab*, 217 F.3d 1365, 1371 (Fed. Cir. 2000); *Al-Site Corp. v. VSI Int. Inc.*, 174 F.3d 1308 (Fed. Cir. 1999). It is respectfully submitted that the Examiner has not identified any objective reason, beyond a mere statement that it would have been obvious to one skilled in the art, to modify the Ikeguchi reference. Therefore, applicant respectfully submits that this § 103 rejection is improper and should be withdrawn.


In light of the above arguments, the applicant respectfully submits that claim 18 is allowable and requests that the Examiner withdraw the § 103 rejections of claim 18 and the claims depending therefrom (claims 19 and 23).

**VI. CONCLUSION**

In light of the foregoing, the applicant respectfully submits that all of the pending claims are in condition for allowance. All issues raised by the Examiner have been addressed, an early and favorable action on the merits is earnestly solicited.

Respectfully submitted,

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